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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0335; FRL-10019-55]

Pyriofenone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyriofenone in or on fruit, small vine climbing subgroup 13-07E, except grape; grape and grape, raisin. ISK BIOSCIENCES Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0335, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0335 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0335, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of August 5, 2020 (85 FR 47330) (FRL-10012-32), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8808) by ISK BIOSCIENCES Corporation, 7470 Auburn Road, Suite A, Concord, OH, 44077. The petition requested that 40 CFR 180.660 be amended by establishing tolerances for residues of the fungicide, pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, in or on fruit, small vine climbing subgroup 13-07E, except grape at 1.5 parts per million (ppm); grape at 0.8 ppm; and grape, raisin at 2.5 ppm. In addition, although not mentioned in EPA's document, ISK's petition also requested that the currently established tolerances for residues of pyriofenone in/on fruit, small vine climbing subgroup 13-07D at 1.5 ppm be removed from 40 CFR 180.660, as establishment of the requested tolerances for subgroup 13-07E and grape include all the crops in subgroup 13-07D. That document referenced a summary of the petition prepared by ISK BIOSCIENCES Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. No comment was received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty

that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyriofenone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyriofenone follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and republishing the same sections is unnecessary; therefore, EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for pyriofenone, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pyriofenone and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. For a discussion of the Toxicological Profile of pyriofenone, see Unit III.A. of the May 30, 2019 rulemaking (84 FR 24983) (FRL-9993-11).

Toxicological Points of Departure/Levels of Concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the May 30, 2019 rulemaking.

Exposure Assessment. EPA's exposure assessment remains unchanged from what was done in support of the May 30, 2019 rulemaking. EPA's aggregate exposure assessments include exposures from food, drinking water and residential sources, and there have been no changes since the last assessment. For a discussion of EPA's assessment of aggregate exposures, see Unit III.C. of the May 30, 2019 rulemaking.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10X to 1X for all exposure scenarios. The reasons for that decision are articulated in Unit III.D. of the May 30, 2019 rulemaking.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Pyriofenone is not expected to pose an acute risk, due to the lack of acute adverse effects in the database. Chronic dietary risks are below the Agency's level of concern: 6.9% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the group with the highest exposure. There are no residential uses for pyriofenone; therefore, the chronic aggregate risk is limited to the chronic dietary risk and is not of concern. Short- and

intermediate-term aggregate risks are addressed by the chronic aggregate risk estimates and are not a concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general populations, or to infants and children for aggregate exposure to pyriofenone residues. More detailed information on the subject action can be found at *https://www.regulations.gov* in the document entitled, "Pyriofenone. Human Health Risk Assessment for the Section 3 Registration on Fruiting Vegetables (Crop Group 8-10)" in the docket ID number EPA-HQ-OPP-2020-0335 and the document titled, "Pyriofenone. Human Health Risk Assessment for the Section 3 Registration on Fruiting Vegetables (Crop Group 8-10)" in docket ID number EPA-HQ-OPP-2018-0677.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the May 30, 2019 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for pyriofenone in or on grape at 0.8 ppm and grape, raisin at 2.5 ppm. The U.S. tolerances for these commodities are harmonized with these MRLs.

C. Revisions to Petitioned-For Tolerances

Under FFDCA section 408(d)(4)(A)(i), EPA may establish tolerances that vary from those sought by the petition. The tolerance level has been modified to be consistent with the Agency's rounding class practices.

D. International Trade Considerations

In this Final Rule, EPA is establishing an individual tolerance for grape at 0.8 ppm, which is lower than the current allowed amount of residue on grape, by virtue of its inclusion in the small vine climbing fruit subgroup 13-07D at 1.5 ppm. The Agency is reducing this tolerance to harmonize with the Codex MRL on grape, and available residue data demonstrate that this tolerance is sufficient to cover residues on this commodity.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. To accommodate this reasonable interval, EPA is establishing an expiration date for the existing tolerance for small vine climbing fruit subgroup 13-07D to allow those tolerances to remain in effect for a period of 6 months after the effective date of this rule. At the end of that 6-month period, the existing tolerances for subgroup 13-07D will no longer be valid; residues on grape will need to comply with the new grape tolerance and residues on other commodities in that subgroup will need to comply with the new subgroup 13-07E tolerance.

This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance level is supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of pyriofenone, (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl) methanone, in or on fruit, small vine climbing subgroup 13-07E, except grape at 1.5 ppm; grape at 0.8 ppm; and grape, raisin at 2.5 ppm. EPA is also establishing an expiration date for the existing tolerance for fruit, small vine climbing subgroup 13-07D.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 8, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.660, amend the table in paragraph (a) by:

a. Designating the table as Table 1;

b. Revising the entry for "Fruit, small vine climbing, subgroup 13-07D"; and

c. Adding in alphabetical order entries for "Fruit, small vine climbing, subgroup 13-07E, except grape"; "Grape"; and "Grape, raisin".

The additions and revision read as follows:

§ 180.660 Pyriofenone; tolerances for residues.

* * * * *

Table 1 to paragraph (a)

Commodity	Parts per million
* * * * * * *	
Fruit, small vine climbing subgroup 13-07D[1]	1.5
Fruit, small vine climbing subgroup 13-07E, except grape	1.5
Grape	0.8
Grape, raisin	2.5
* * * * * * *	

[1] This tolerance expires on October 6, 2021.

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[FR Doc. 2021-06271 Filed: 4/2/2021 8:45 am; Publication Date: 4/5/2021]